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Bill J. Peck

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EXAMINER

WILDER, CYNTHIA B

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 07/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/813,331

Applicant(s)

PECK ET AL

Examiner

Cynthia B. Wilder, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/20/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 17-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/29/2004 7-3-06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION***Election/Restrictions***

1. Applicant's election with traverse of Group I, claims 1-16 in the reply filed on April 20, 2006 is acknowledged. The traversal is on the ground(s) that the claims of Group II, III and IV along with the elected claims of Group I for examination in this application do not impose an undue burden to the Examiner. Applicant states that in the present case, the claims of Groups II, III and IV relate to the array produced by the group I claims, methods of using the array and a device for performing the elected claims. Applicant states that accordingly, little, if any additional searching should be required for the claims of Groups II, III and IV and therefore the examination of the claims of Group II, III and IV together with the claims of elected Group I should impose little, if any, additional burden on the Examiner. Applicant concludes that since the present application clearly does not impose a serious burden on the Examiner, the Examiner is clearly instructed by the MPEP to examine the entire application. Applicant thus request the restriction requirement be withdrawn.

The arguments have been thoroughly reviewed and considered, but are not found persuasive because the searches of Groups II, III and IV along with the elected Group I are coextensive. Specifically, prior art which would teach the products of Groups II, and IV or the detection method of Group III would not necessarily teach a method of producing an array of nucleic acids as recited in the Group I. Likewise, a search burden exist because searching the inventions of Group II, III and IV along with the invention of Group I would additionally encompass an extensive review of patents

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and non-patent literature directed to any type of array associated with nucleic acids; arrays comprising binding complex data; a commercial product, such as e.g., kit comprising an array; computer readable medium; and a structure search for an apparatus, all of which are not required by the invention of Group I. Thus, the Examiner asserts that a serious search burden exist if the different inventions of Groups I-IV are searched together because the different invention contain non-overlapping subject matter. Accordingly, claims 17-27 are withdrawn from consideration as being drawn to a non-elected invention. Claims 1-16 are addressed in this Office Action. The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claim 7, 8, 10 and 11 are objected to because of the following informalities:

- (a) Claim 7 is objected to because it depends from "Claim 8", not any of the preceding claims.
- (b) Claim 8 is objected to because it depends from "Claim 10", not any of the preceding claims.
- (c) Claim 10 is objected to because it depends from "Claim 11", not any of the preceding claims.
- (d) Claim 11 is objected to because it depends from itself.

A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim.

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A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. In general, applicant's sequence will not be changed. See MPEP § 608.01(n). For the purpose of examination, the claims 7, 8, 10 and 11 will be considered as being dependent from the Claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claim 11 lacks proper antecedent basis at "said stratified fluid interface" because the claim 1 from which it depends does not recite "a stratified fluid interface". It is suggested amending the claims such that the claims language agree.

Claim Rejections - 35 USC § 102(b)

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldberg et al (US 5,959,098, patent date September 1999). Regarding claim 1, Goldberg et al teach a method of producing an array of at least two different nucleic acid ligands covalently bonded to a surface of a substrate, said method comprising: (a) contacting blocked nucleoside monomers to at least a first location and a second location of a substrate surface displaying functional groups under conditions sufficient for said blocked nucleoside monomers to covalently bond to said surface in said first and second locations to produce a substrate surface displaying covalently bound blocked monomers; (b) contacting said surface displaying blocked nucleoside monomers with an oxidation fluid to produce an oxidized surface; (c) contacting said oxidized surface with a deblocking fluid; (d) removing deblocking fluid from said deblocked surface by displacing said deblocking fluid from said surface with a wash fluid; and (e) reiterating steps (a) to (d) at least once to produce said array of at least two different nucleic acid ligands (col. 2, lines 12-23; col. 4, lines 21-65; col. 9, line 53 to col. 10, line 52; col. 28, lines 1-42; see also Examples 2-4).

¹Regarding claim 11, Goldberg teaches sensing movement of the solutions across the surface with the use of the device comprising the flow cell (col. 15, lines 1 to col. 16, line 5).

Regarding claim 12-14, Goldberg et al teach the method according claim 1, wherein the steps (b), (c) and (d) occur in the same flow cell (col. 14, line 35 to col. 16,

¹ Note**Neither the specification nor claims provide a limiting definition of "a stratified fluid interface". Accordingly, the claims are being interpreted by the Examiner as a movement of a solution(s) across a surface as with the use of a pump, device or apparatus.

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line 5; especially, col. 15, lines 4-13). Therefore, Goldberg et al meets the limitations of claims 1 and 11-14

Claim Rejections - 35 USC § 102(b) cont.

7. Claims 1, 7-9, 11, 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Dellinger et al (US 2002/0058802 A1, filing date July 27, 2001). Regarding claim 1, Dellinger et al teach a method of producing an array of at least two different nucleic acid ligands covalently bonded to a surface of a substrate, said method comprising: (a) contacting blocked nucleoside monomers to at least a first location and a second location of a substrate surface displaying functional groups under conditions sufficient for said blocked nucleoside monomers to covalently bond to said surface in said first and second locations to produce a substrate surface displaying covalently bound blocked monomers; (b) contacting said surface displaying blocked nucleoside monomers with an oxidation fluid to produce an oxidized surface; (c) contacting said oxidized surface with a deblocking fluid; (d) removing deblocking fluid from said deblocked surface by displacing said deblocking fluid from said surface with a wash fluid; and (e) reiterating steps (a) to (d) at least once to produce said array of at least two different nucleic acid ligands (0020-0023, 0037-0038, 0052, 0087-0091 and Examples I and II; see also Figures 3-5, especially Figure 5).

Regarding claim 7, Dellinger et al teach the method according to claim 1, wherein said wash fluids is an organic fluid (0090 and 0103).

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Regarding claim 8, Dellinger et al teach the method according to claim 1, wherein said wash fluid is acetonitrile (0103).

¹Regarding claims 9 and 11, Dellinger et al teach the method of claim 1, wherein said deblocking fluid is displaced from said surface with a wash fluid according step (b) by flowing said wash fluid across said surface and said method further comprise sensing movement of the fluid across a surface (see Table 3 at paragraph 0112 which shows the different cycles and wash steps; see also 0130 which discloses an apparatus which performs the synthesis cycles 0135).

Regarding claim 15, Dellinger et al teach the method according to claim 1, wherein said surface is contacted with a capping solution prior to the said deblocking step (see Table 3 at paragraph 0112).

Regarding claim 16, Dellinger et al teach the method according to claim 1, wherein said blocked nucleoside monomers are contacted with said surface by pulse-jet deposition (0087 and 0088). Therefore, Dellinger et al meet the limitations of the claims 1,7, 8, 15, and 16 of the instant invention.

Claim Rejections - 35 USC § 102(e)

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 9-11 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Sana et al (Us 2005/0019786 A1, filing date November 25, 2003).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 1, Sana et al teach a method of producing an array of at least two different nucleic acid ligands covalently bonded to a surface of a substrate, said method comprising: (a) contacting blocked nucleoside monomers to at least a first location and a second location of a substrate surface displaying functional groups under conditions sufficient for said blocked nucleoside monomers to covalently bond to said surface in said first and second locations to produce a substrate surface displaying covalently bound blocked monomers; (b) contacting said surface displaying blocked nucleoside monomers with an oxidation fluid to produce an oxidized surface; (c) contacting said oxidized surface with a deblocking fluid; (d) removing deblocking fluid

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from said deblocked surface by displacing said deblocking fluid from said surface with a wash fluid; and (e) reiterating steps (a) to (d) at least once to produce said array of at least two different nucleic acid ligands (0075-0084; see also Figures 1-3, especially Figure 3).

¹Regarding claims 9 and 11, Sana et al teach the method of claim 1, wherein said deblocking fluid is displaced from said surface with a wash fluid according step (b) by flowing said wash fluid across said surface and said method further comprise sensing movement of the fluid across a surface (0075 where Sana teach the washing step after the deblocking step, 0084 and 0109).

Regarding claim 10, wherein said the solution used in the synthesis reaction are flowed across the surface at a rate of about 10 m/s to about 20 m/s or greater, which encompasses the range recited therein (0089).

Regarding claim 16, Sana et al teach the method according to claim 1, wherein said blocked nucleoside monomers are contacted with said surface by pulse-jet deposition (0084, 0089 and 0109). Therefore, Sana et al meet the limitations of the claims 1, 9-11

Claim Rejections - 35 USC § 102(b)/103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 2-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Dellinger et al as previously applied above. Regarding claim 2-4, Dellinger et al teach a method of producing an array of at least two different nucleic acid ligands covalently bonded to a surface of a substrate comprising a number of method steps wherein TCA in dichloromethane is used as the deblocking agent (see example 1) and acetonitrile (0103) is used as the washing fluid. The preceding rejection is based on the judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because Dellinger is silent with regards to the density of the deblocking agent, TCA; or the washing fluid, acetonitrile. However, the density of the deblocking fluid and washing fluid are inherent properties of the solvents, TCA and acetonitrile. It is commonly known in the art based on standard physical data that TCA has a density of 1.34 and acetonitrile has a density of 0.8. Therefore, it would be obvious to one of ordinary skill in the art that acetonitrile has a lower density than TCA. The burden is on Applicant to prove that the densities of these solvents are not inherent properties and are therefore not different from each other.

Regarding claims 5 and 6, Dellinger et al teach wherein the wash fluid is acetonitrile. The preceding rejection is based on the judicial precedent following *In re Fitzgerald*, 205 USPQ 594 because Dellinger is silent with regards to the viscosity of the washing fluid, acetonitrile. However, it is commonly known in the art based on standard physical data that acetonitrile has a viscosity of 0.38 cP. Therefore, it would be obvious to one of ordinary skill in the art that acetonitrile has a low viscosity that does not

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exceed about 1.2 cP. The burden is on Applicant to prove the viscosity of acetonitrile is not an inherent property and is therefore not low.

Conclusion

12. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CYNTHIA WILDER
PATENT EXAMINER

6/30/06